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(Reaffirmed 2006)

Indian Standard
TRACHEOSTOMY TUBES
PART 2 BASIC REQUIREMENTS

भारतीय मानक
श्वास नली शल्य क्रिया नलिकाएं
भाग 2 आधारभूत अपेक्षाएं

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MANAK BHAVAN, 9 BAHADUR SHAH ZAFAR MARG
NEW DELHI 110002

January 1990

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Indian Standard

TRACHEOSTOMY TUBES

PART 2 BASIC REQUIREMENTS

NATIONAL FOREWORD

This Indian Standard (Part 2), which is identical with ISO 5366/2-1985 'Tracheostomy tubes — Part 2 Basic requirements', issued by the International Organization for Standardization (ISO), was adopted by the Bureau of Indian Standards on 25 April 1988 on the recommendation of the Anaesthetic, Resuscitation and Allied Equipment Sectional Committee (CPDC 13) and approval of the Consumer Products and Medical Instruments Division Council.

The text of ISO standard has been approved as suitable for publication as Indian Standard without deviations. Certain conventions are, however, not identical to those used in Indian Standards. Attention is particularly drawn to the following:

a) Wherever the words 'International Standard' appear referring to this standard, they should be read as 'Indian Standard'.

b) Comma (,) has been used as a decimal marker while in Indian Standards the current practice is to use a point (.) as the decimal marker.

This Indian Standard is in two parts. Other part is:

IS 12505 (Part 1) : 1988 Tracheostomy tubes: Part 1 Connectors (adoption of ISO 5366/1-1986)

CROSS REFERENCE

In this Indian Standard, the following International Standards are referred to. Read in their respective places the following:

International Standard	*Indian Standard*	*Degree of Correspondence*
ISO 5361/1-1984 Tracheal tubes — Part 1 : General Requirements	IS : 12504 (Part 1)-1988 Specification for tracheal tubes: Part 1 General requirements	Identical
ISO 5361/2-1984 Tracheal tubes — Part 2 : Tracheal and Naso-tracheal tubes of magill type (plain and cuffed)	IS : 12504 (Part 2)-1988 Specification for tracheal tubes: Part 2 Oro-tracheal tubes and nasotracheal tubes of the Magill type (plain and cuffed)	Identical
ISO 5361/4-1984 Tracheal tubes — Part 4 : Cole type	IS : 12504 (Part 4)-1988 Specification for tracheal tubes: Part 4 Cole type	Identical
ISO 5361/5-1984 Tracheal tubes — Part 5 : Requirements and methods of test for cuffs and tubes	IS : 12504 (Part 5)-1988 Specification for tracheal tubes: Part 5 Requirements and methods of test for cuffs and tubes	Identical
ISO 594/1 : 1986 Conical fittings with a 6% (Luer) taper for syringes, needles and certain other medical equipment — Part 1 : General requirements	IS : 3234 (Part 1)-1986 Conical fittings with a 6 percent (Luer) taper for syringes, needles and other medical equipment : Part 1 General requirements (*second revision*)	Identical
ISO 5366/1-1985 Tracheostomy tubes — Part 1 : Connectors	IS : 12505 (Part 1)-1988 Tracheostomy tubes : Part 1 Connectors	Identical

The technical committee responsible for the preparation of this standard has reviewed the provisions of the following ISO standards and has decided that they are acceptable for use in conjunction with this standard:

ISO 4135 : 1979 Anaesthesiology — Vocabulary

ISO 5356/1-1987 Anaesthetic and respiratory equipment — Conical connectors — Part 1: Cones and sockets.

0 Introduction

This part of ISO 5366 is one of a series dealing with anaesthetic equipment and medical breathing machines, and is concerned with the basic requirements and method of size designation of tracheostomy tubes made of plastics material. Although specialized tubes and tubes made of rubber or metal have been excluded from the scope of this document, some of these tubes may have the size designated by the inside diameter as required by this specification and that for tracheal tubes (see ISO 5361/1, ISO 5361/2 and ISO 5361/4).

The new method of describing tube dimensions has been devised with the aim of assisting the clinician in the selection of a suitable tube. Because the stomal fit is often critical, it was considered essential that the outside diameter should be stated for each size of tube.

With the exception of size designation, it was considered premature to specify detailed requirements for paediatric tubes and dimensions for all tubes so as not to restrict developments in design.

1 Scope and field of application

This part of ISO 5366 specifies basic requirements for tracheostomy tubes made of plastics material. Such tubes are primarily designed for patients who may require anaesthesia, artificial ventilation or other respiratory support, but need not be restricted to these uses. Provision is made for size designation, size range and for such optional features as cuffs and inner tubes.

2 References

ISO 594/1, *Conical fittings with a 6 % (Luer) taper for syringes, needles and certain other medical equipment — Part 1 : General requirements.* [1]

ISO 4135, *Anaesthesiology — Vocabulary.*

ISO 5356/1, *Breathing attachments for inhalation anaesthesia apparatus, lung ventilators and resuscitators — Part 1 : Conical fittings and adaptors for breathing systems.* [2]

ISO 5361, *Tracheal tubes —*

Part 1 : General requirements.

Part 2 : Oro-tracheal and naso-tracheal tubes of the Magill type (plain and cuffed).

Part 4 : Cole tubes.

Part 5 : Requirements and methods of test for cuffs and tubes.

ISO 5366/1, *Tracheostomy tubes — Part 1 : Connectors.*

3 Definitions

NOTE — The following definitions are taken from ISO 4135 except where marked with an asterisk.

3.1 tracheostomy tube : Tube designed for insertion into the trachea through a tracheostomy.

3.2 machine end* : That end of the tracheostomy tube which is intended to project from the patient.

3.3 patient end* : That end of the tracheostomy tube which is intended to be inserted into the trachea.

3.4 nominal length* : Distance from the neck-plate to the patient end along the centre line (see figure 2).

When the neck-plate is movable, the nominal length is variable.

3.5 outer tube* : That part of the tracheostomy tube which is normally in contact with the tissues.

3.6 inner tube* : Tube which fits closely to the inside contours of the outer tube (tracheostomy tube).

3.7 inner tube lock* : Device by which the inner tube is secured in position within the outer tube.

3.8 neck-plate lock* : Device by which an adjustable neck-plate may be secured.

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[1] At present at the stage of draft. (Revision of ISO/R 594-1967.)

[2] At present at the stage of draft.

3.9 cuff : Inflatable sleeve fitted near the patient end of the tracheostomy tube to provide an effective seal between the tube and the trachea.

3.10 inflating tube : Tube through which the cuff is inflated.

3.11 pilot balloon :Balloon fitted to the inflating tube to indicate inflation of the cuff.

3.12 neck-plate (shield)* : That part of the device which approximates to the contour of the patient's neck and is used to secure the tube in position.

3.13 introducer (obturator)* : Specially adapted stylet to facilitate the introduction of the outer tube into the trachea.

3.14 bevel : Slanted portion at the patient end of the tracheostomy tube.

3.15 angle of bevel : Acute angle between the plane of the bevel and the longitudinal axis of the tracheostomy tube at the patient end.

4 Size designation

The size of a tracheostomy tube (outer tube) shall be designated by the nominal inside diameter (ID) of the tube as measured at the minimum diameter, in accordance with the table.

Table — Size range of tracheostomy tubes

Dimensions and tolerances in millimetres

Designated size (nominal inside diameter, ID)	Inside diameter and tolerance
2,5	2,5 ± 0,15
3,0	3,0 ± 0,15
3,5	3,5 ± 0,15
4,0	4,0 ± 0,15
4,5	4,5 ± 0,15
5,0	5,0 ± 0,15
5,5	5,5 ± 0,15
6,0	6,0 ± 0,15
6,5	6,5 ± 0,20
7,0	7,0 ± 0,20
7,5	7,5 ± 0,20
8,0	8,0 ± 0,20
8,5	8,5 ± 0,20
9,0	9,0 ± 0,20
9,5	9,5 ± 0,20
10,0	10,0 ± 0,20
11,0	11,0 ± 0,20

5 Dimensions and other information to be provided

5.1 In addition to clause 4, the following dimensions and information shall be provided :

a) The overall nominal centre line length in millimetres from the patient side of the neck-plate to the patient end including the bevel, if present (see figure 2).

b) The nominal outside diameter (OD) expressed in millimetres as measured at the maximum diameter. For tracheal tubes of 6,0 mm inside diameter (ID) and smaller, the actual outside diameter shall be within ± 5 % of the stated outside diameter.

c) Means to enable the user to determine the size and shape of the tube without compromising its sterility, for example a full scale drawing or facsimile in either case with or without dimensions, or by the use of a transparent package.

5.2 Other information, if provided, by the manufacturer or supplier :

a) Dimensions A and B as shown in figure 2.

b) The range of measurements for dimension B when the neck-plate on the tracheostomy tube is adjustable. If a tracheostomy tube has a swivel neck-plate, dimension B shall be measured with the neck-plate normal to the main axis.

c) The angle θ (as shown in figure 2).

6 Materials

6.1 Tracheostomy tubes, including cuffs, in their ready-for-use state shall be compatible with the human tissues with which they are intended to be used, as determined by the implantation test given in the annex.

6.2 The material used for the manufacture of the tubes shall have sufficient rigidity to allow the construction of a tube with the thinnest possible wall which, at the same time, maintains resistance to kinking. When in place it shall be flexible and soft enough to conform to the patient's anatomy without exerting undue pressure on the body tissues.

6.3 When not in use the tube shall maintain its intended shape when stored in accordance with the manufacturer's instructions.

NOTES

1 Unless designated for single use, tracheostomy tubes should be reasonably resistant to deterioration by methods of cleaning, disinfection and sterilization as recommended by the manufacturer or the supplier. Such tubes should withstand accepted methods of steam sterilization.

The recommended method or methods of sterilization should not produce changes in the tube material which will render the tracheostomy tube incompatible with human tissues with which it is intended to be used (see the annex).

2 Tracheostomy tubes under normal conditions of use should be reasonably resistant to deterioration by anaesthetic vapours and gases.

3 Tracheostomy tubes should be readily detectable by X-ray either by the nature of the material of which they are made or by the provision of a marker at the patient end.

7 Design and finish

7.1 Finish

Tracheostomy tubes, including the neck-plate, shall have smooth external and internal surfaces. The cuff shall have a smooth surface.

7.2 Machine end

The machine end of tracheostomy tubes shall be in accordance with ISO 5366/1.

7.3 Neck-plate

Tracheostomy tubes shall be provided with a neck-plate which shall be rounded at the edges, and its shape shall adapt to the contour of the patient's neck. The neck-plate shall be provided with holes or other means to permit easy attachment to the patient. Unless it is adjustable or is of a type that swivels (see 7.4), the neck-plate or other means of attachment to the patient shall be permanently bonded to the tube.

7.4 Adjustable neck-plate

If a tracheostomy tube has an adjustable neck-plate, that plate shall be securable to the tube.

7.5 Lumen

The lumen of the tracheostomy tube shall be essentially circular in a plane at right angles to the long axis.

7.6 Inner tube

The inner tube shall extend to the patient end and not more than 2,0 mm beyond the patient end of the tracheostomy tube.

7.7 Cuff

7.7.1 A cuff, if provided, shall be securely bonded to the tube.

7.7.2 Cuffs of tracheostomy tubes shall satisfy the requirements of ISO 5361/5.

7.8 Inflating tubes for cuffs

7.8.1 Inflating tube

The inflating tube shall have an outside diameter of not more than 3,0 mm. The secondary (inflation) lumen shall not encroach on the lumen of the tracheostomy tube by more than 10 % of the inside diameter and should not project substantially on the outside surface. The point of attachment of the inflating tube to the tracheostomy tube shall be outside the tracheal wall when in use.

7.8.2 Pilot balloon

The inflating tube shall have a pilot balloon and/or other means to indicate inflation of the cuff. This (these) device(s) may also serve as a pressure indicating or limiting device. Neither the inflating tube nor any device shall act as a non-return valve to prevent the intentional evacuation of the cuff.

7.8.3 Free end of inflating tubes for cuffs

The end of the inflating tube may be open or sealed with a closure device or inflation valve, but in all instances it shall be capable of accepting a male conical fitting with a 6 % taper (Luer), in accordance with ISO 594/1. The length (see figure 1, dimension l_1) of the free end of inflating tubes shall be not less than 40 mm unless an inflation valve or closure device is provided.

If an inflation valve or closure device is provided, the length (see figure 1, dimension l_2) between the pilot balloon (or other device) and the 6 % conical fitting shall be not less than 10 mm (for clamping) unless the pilot balloon and valve are integral.

7.9 Patient end

7.9.1 The patient end shall be free from sharp edges.

7.9.2 If a bevel is present the angle of bevel shall be not less than 50° (see inset in figure 1).

8 Introducer (obturator)

If provided, the introducer should be easily removable after introduction of the tracheostomy tube into the patient.

9 Packaging for tracheostomy tubes supplied sterile

Each tracheostomy tube supplied in a sterile condition shall be contained in an individual pack. The pack shall serve as a microbiological barrier. The pack shall permit the aseptic extraction of the contents and shall not be capable of re-closure without clearly revealing that it has been opened.

10 Marking

10.1 Marking of tracheostomy tubes

The neck-plate and/or tracheostomy tube shall be marked with the following :

a) the designated size (nominal inside diameter) expressed in millimetres in accordance with clause 4;

b) the nominal outside size expressed in millimetres in accordance with clause 5;

c) the name and/or trade mark of the manufacturer.

All markings shall be visible when the tube is placed *in situ*.

10.2 Labelling of unit packs

Individual packs or a package insert shall be clearly labelled to indicate the following :

a) a description of contents;

b) the designated size in accordance with clause 4 and other basic dimensions in accordance with clause 5;

c) the name and/or trade mark of the manufacturer and/or supplier;

d) an identification reference to the batch or the date of manufacture;

e) if relevant, instructions for disinfection, cleaning and sterilization;

f) whether they are sterile and whether single use is intended.

10.3 Labelling of inner tube unit packs

Individual packs shall be clearly labelled to indicate the following :

a) the size designation of the tracheostomy tube (outer tube) into which it is designed to fit;

b) the inside diameter (ID) of the inner tube;

c) a description of the contents;

d) the name and/or trademark of the manufacturer and/or supplier;

e) an identification reference (batch number);

f) whether they are sterile and whether single use is intended.

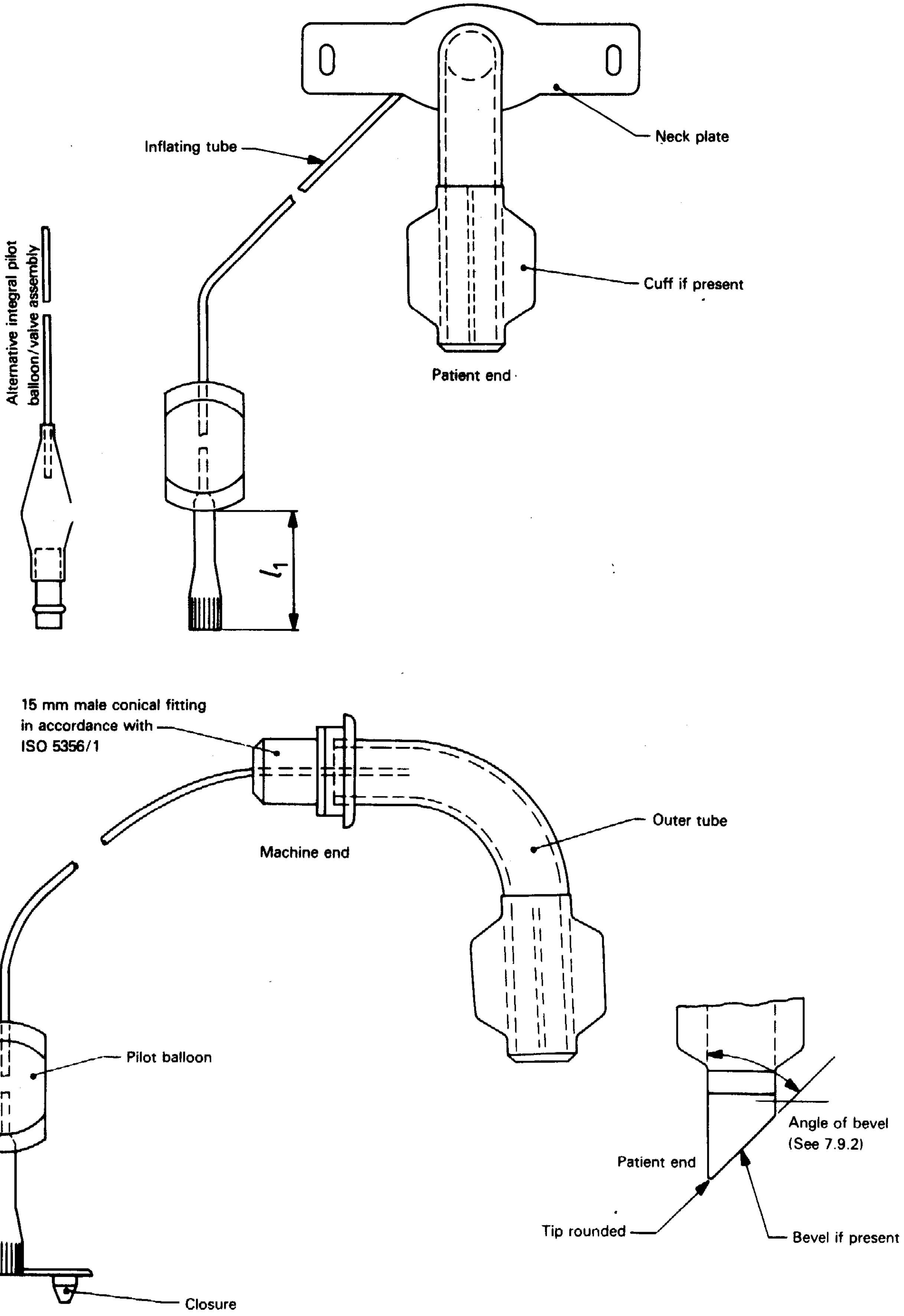

Figure 1 — Typical tracheostomy tube

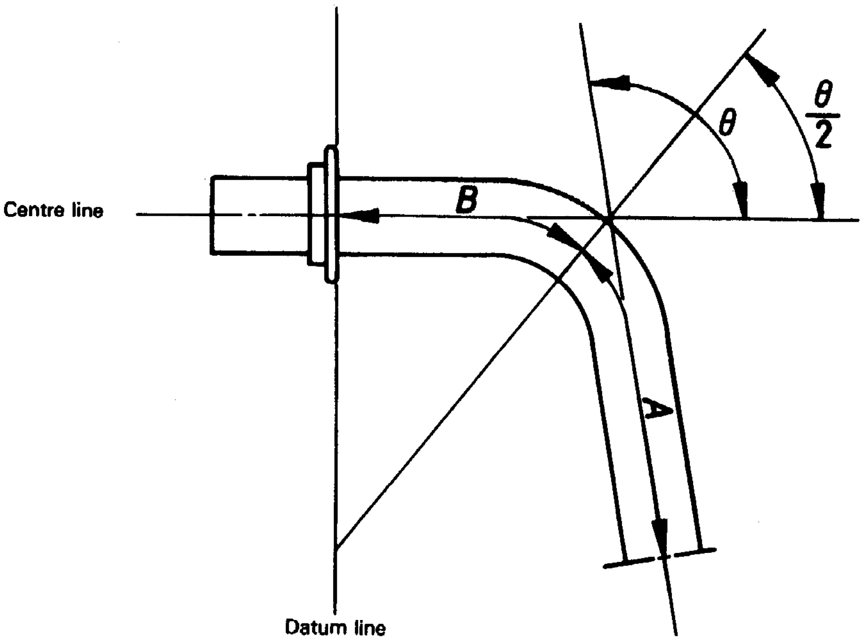

Figure 2 — Basic dimensions of tracheostomy tubes

Annex

Implantation test[1]

(This annex forms part of the standard.)

A.1 General

The implantation test is designed for the evaluation of a plastics material in direct contact with living tissue. Care shall be taken in the preparation of the implant strips and their proper implantation under aseptic conditions.

A.2 Preparation of test samples

Prepare for implantation eight strips of the sample and four strips of USP Negative Control Plastic RS[2]. Each strip shall measure not less than 10 mm × 1 mm. The edges of the strips should be as smooth as possible to avoid additional mechanical trauma upon implantation. Strips of the specified minimum size shall be implanted by means of a hypodermic needle such as a 15 gauge needle with intravenous point and of 19 mm (0.75 in) cannula length, and a sterile trocar. Use either presterilized needles into which the sterile plastics strips are aseptically inserted, or insert each clean strip into a needle, the cannula and hub of which are protected with an appropriate cover, and then subjected to the appropriate sterilization procedure.

NOTE — Allowance should be made for proper de-gassing if agents such as ethylene oxide are used.

A.3 Test animal

Select healthy, adult rabbits weighing not less than 2,5 kg, and whose paravertebral muscles are sufficiently large in size to allow for implantation of the test strips. Do not use any muscular tissue other than the paravertebral site. The animals may be anaesthetized with a commonly used anaesthetic agent to a degree deep enough to prevent muscular movements, such as twitching.

A.4 Procedure

Perform the test in a clean area. On the day of the test or up to 20 h before testing, clip the fur of the animals on both sides of the spinal column. Remove loose hair by means of vacuum.

Implant four strips of the sample into the paravertebral muscle on one side of the spine of each of two rabbits, 2,5 to 5 cm from the mid-line and parallel to the spinal column, and about 2,5 cm apart from each other. In a similar fashion implant two strips of USP Negative Control Plastic RS in the opposite muscle of each animal. Insert a sterile stylet into the needle to hold the plastics strips in the tissue while withdrawing the needle. If excessive bleeding is observed after implantation of a strip, place a duplicate strip at another site. Close the incision after implantation is complete.

Keep the animals for a period of not less than 72 h and sacrifice them at the end of the observation period by administering an overdose of an anaesthetic agent. Allow sufficient time to elapse for the tissue to be cut without bleeding. Examine macroscopically the area of the tissue surrounding the centre portion of each implant strip. Use a magnifying lens if necessary. The tissue immediately surrounding the USP Negative Control Plastic RS strips appears normal and entirely free from haemorrhage, film, or encapsulation. The requirements of the test are met if, in each rabbit, the reaction to not more than one of the four sample strips is significantly greater than that to the strips of USP Negative Control Plastic RS.

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[1] Taken from US Pharmacopeia.

[2] USP Negative Control Plastic RS is a trade name for a commercial product available from the US Pharmacopeal Convention Inc., 12601 Twinbrook Parkway, Rockville, Maryland 20852, USA. At present, no other products intended for this purpose are known to be available commercially. This information is given for the convenience of the users of this International Standard and does not constitute an endorsement of this product by ISO.

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